IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Re: Application No. ***09/834,208***	Confirmation No. 3950
Filing Date : April 13, 2001	Examiner: M. Mendoza
Appellant: G. Thomas Wolf	Art Unit: 3731
For: **Oxygen Mask**	Docket No. 0022.010001

APPEAL BRIEF

Mail Stop: APPEAL BRIEF - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Appellant submits the present Appeal Brief subsequent to the filing of a Notice of Appeal and After-Final Reply on June 18, 2007. The Office Action mailed on January 22, 2007 was made final by the Examiner.

The Appeal Brief is presented in the following format:

(A) Identification page setting forth the Appellant's name(s), the application number, the filing date of the application, the title of the invention, the name of the examiner, the art unit of the examiner and the title of the paper (i.e., Appeal Brief);

(B) Table of Contents page(s);

(C) Real party in interest page(s);

(D) Related appeals and interferences page(s);

(E) Status of claims page(s);

(F) Status of amendments page(s);

(G) Summary of claimed subject matter page(s);

(H) Grounds of rejection to be reviewed on appeal page(s);

(I) Argument page(s);

(J) Claims appendix page(s);

(K) Evidence appendix page(s);

(L) Related proceedings appendix page(s).

It is not believed that an extension of time or fees are required beyond those that may otherwise be provided for in documents accompanying this paper. However, if an extension of time is necessary to prevent abandonment of this application, then such extension of time is hereby petitioned under 37 C.F.R. § 1.136(a).

Contents

Remarks

Appellant hereby offers the following remarks.

(B) REAL PARTY IN INTEREST:

The real party in interest is G. Thomas Wolf, an independent inventor.

(C) RELATED APPEALS AND INTERFERENCES

There are no related Appeals and/or Interferences.

(D) STATUS OF CLAIMS

Claims 5-10, 12-15, 17, and 18 are under consideration, with claims 5, 8 and 14 being independent claims. Claims 1-4 were originally filed. Claims 5-10 were added in the amendment filed February 8, 2004, claims 11-13 were added in the amendment filed July 19, 2004 and claims 14-18 were added in the amendment filed June 29, 2005. Claim 4 was cancelled in the amendment filed February 8, 2004, claims 1-3 and 11 were cancelled in the amendment filed June 29, 2005 and claim 16 was cancelled in the amendment filed on June 16, 2006.

The Appellant lists each claim in the case on appeal, and whether it is cancelled, rejected, objected to, etc. The claims on appeal are the following:

1. (Cancelled; Amended in the reply filed August 27, 2002) An oxygen mask having an improved means for being secured over the nose and mouth of a patient, the improvement comprising: a pair of elastic bands, both ends of each pair affixed at points of attachment to each of both sides of said mask, said bands extendible to loop over and around each ear of the patient

and adjustably securable to said patient by pulling the ends anteriorally through said points of attachment.

2. (Cancelled) The oxygen mask according to claim 1 wherein the elastic bands are affixed at four separate points on the mask.

3. (Cancelled) The oxygen mask according to claim 1 wherein the elastic bands are affixed at two separate points on the mask.

4. (Cancelled) The oxygen mask according to claim 1 wherein the elastic bands are adjustable.

5. (Rejected) An oxygen mask comprising a pair of elastic bands, both ends of each pair affixed at points of attachment to each of both sides of said oxygen mask, said bands extendible to loop over and around each ear of the patient and adjustably securable to said patient by pulling the ends anteriorally through said points of attachment.

6. (Rejected) The oxygen mask according to claim 5 wherein the elastic bands are affixed at four separate points on the mask.

7. (Rejected) The oxygen mask according to claim 5 wherein the elastic bands are affixed at two separate points on the mask.

8. (Rejected) An oxygen mask having an improved means for being secured over the nose and mouth of a patient, wherein the oxygen mask comprises a pair of elastic bands, both ends of each pair affixed at points of attachment to each of both sides of said oxygen mask, said bands extendible to loop over and around each ear of the patient and adjustably securable to said patient by pulling the ends anteriorally through said points of attachment.

9. (Rejected) The oxygen mask according to claim 8 wherein the elastic bands are affixed at four separate points on the mask.

10. (Rejected) The oxygen mask according to claim 8 wherein the elastic bands are affixed at two separate points on the mask.

11. (Cancelled) The mask of claim 1, wherein said mask comprises a nosepiece wit two exhalation ports covered with a flap valve.

12. (Rejected) The mask of claim 5, wherein said mask comprises a nosepiece with two exhalation ports covered with a flap valve.

13. (Rejected) The oxygen mask of claim 8, wherein said mask comprises a nosepiece with two exhalation ports covered with a flap valve.

14. (Rejected) An oxygen mask for use on a patient, said oxygen mask comprising:

a) a face mask molded from plastic to form a soft, one-piece covering for the mouth and nose of

the patient, comprising a larger part of the mask defined by a face-conforming periphery, having a rim with an enlargement configured to substantially conform to the contour of the nose bridge of the patient;

a first side portion and an opposite second side portion configured to substantially conform to the contour of the face of the patient, and a lower portion configured to substantially conform to the contour of the face of the patient below the mouth so as to form a breathing chamber about the mouth and nostrils of the patient when the oxygen mask is positioned on the patient's face; and

b) a pair of elastic bands, both ends of each pair affixed to each of both sides of said mask, said bands extendible to loop over and around each ear of the patient for holding the face mask snugly against the patient's face, the straps comprising a left and right loop strap;

i) a first loop comprising a strap attached to the periphery of the mask at each of two points of attachment, said strap attached to said attachment points and connected to the face mask proximate the first side of the rim in a spaced apart relation to one another, with at least one loose end of the strap extending anteriorally through the attachment point;

ii) a second loop comprising a strap extending from an opposing side of the loop at a second juncture and being connected to the face mask proximate the second side of the rim in a spaced apart relation to one another, with at least one loose end of the strap extending anteriorally through the attachment point;

iii) wherein said loose ends of the straps extend anteriorally through the attachment point such that adjustment of said straps can be effected by anteriorally pulling the loose ends secured at the attachment points; and

iv) the straps are sized and oriented relative to one another such that when the face mask and the strap assembly are operably donned on the patient each of the first and second straps is positioned substantially around a corresponding ear of the patient and has a length which extends approximately from a front side of the patient's ear to a rear side of the patient's ear to hold the mask securely on the patient's face.

15. (Rejected) The oxygen mask of claim 14, wherein both ends of each of the straps is adjustably connected to the face mask.

16. (Rejected) The oxygen mask of claim 14, wherein one end of each of the straps is adjustably connected to the face mask and the second end of the strap is permanently attached.

17. (Rejected) The oxygen mask of claim 14, which additionally comprises an adapter plug attached adjacent to the nostrils, for the attachment of a tube attached to a device selected from the group consisting of an oxygen reservoir bag, air entrainment device, and nebulizer.

18. (Rejected) The oxygen mask of claim 14, wherein said mask comprises a nosepiece with two exhalation ports covered with a flap valve.

(E) STATUS OF AMENDMENTS

No amendments have been filed subsequent to the Final Rejection of January 22, 2007. The claims presented on appeal are as presented in the amendments filed June 16, 2006. No amendment is currently pending.

(F) SUMMARY OF CLAIMED SUBJECT MATTER

Support in the specification or Figure reference number is given in parentheses.

The claimed invention, independent claim 5, is drawn to an oxygen mask comprising a pair of elastic bands, both ends of each pair affixed at points of attachment to each of both sides of said oxygen mask, said bands extendible to loop over and around each ear of the patient (page 3, lines 1-6) and adjustably securable to said patient by pulling the ends anteriorally through said points of attachment (page 4, lines 12-13).

The claimed invention, independent claim 14 is also drawn to an oxygen mask for use on a patient, said oxygen mask comprising:

a) a face mask molded from plastic to form a soft, one-piece covering for the mouth and nose of the patient (page 3, lines 16-17), comprising a larger part of the mask defined by a face-conforming periphery (page 3, lines 17-18), having a rim with an enlargement configured to substantially conform to the contour of the nose bridge of the patient (Figures 1 and 2, (14), (20));

a first side portion and an opposite second side portion configured to substantially conform to the contour of the face of the patient, and a lower portion configured to substantially conform to the contour of the face of the patient below the mouth so as to

form a breathing chamber about the mouth and nostrils of the patient when the oxygen mask is positioned on the patient's face; (Figures 1 and 2, (12), (14), (22)) and

b) a pair of elastic bands, both ends of each pair affixed to each of both sides of said mask, said bands extendible to loop over and around each ear of the patient for holding the face mask snugly against the patient's face, the straps comprising a left and right loop strap page 3, lines 4-6; page 4, lines 3-10);

i) a first loop comprising a strap attached to the periphery of the mask at each of two points of attachment, said strap attached to said attachment points and connected to the face mask proximate the first side of the rim in a spaced apart relation to one another, with at least one loose end of the strap extending anteriorally through the attachment point (page 4, lines 12-14 and Figures 1 and 2, (24), (26);

ii) a second loop comprising a strap extending from an opposing side of the loop at a second juncture and being connected to the face mask proximate the second side of the rim in a spaced apart relation to one another, with at least one loose end of the strap extending anteriorally through the attachment point (page 4, lines 12-14 and Figures 1 and 2, (24), (26);

iii) wherein said loose ends of the straps extend anteriorally through the attachment point such that adjustment of said straps can be effected by

anteriorally pulling the loose ends secured at the attachment points (page 4, lines 12-14 and 3-7; Figure 1); and

iv) the straps are sized and oriented relative to one another such that when the face mask and the strap assembly are operably donned on the patient each of the first and second straps is positioned substantially around a corresponding ear of the patient and has a length which extends approximately from a front side of the patient's ear to a rear side of the patient's ear to hold the mask securely on the patient's face (Figure 1).

The claims also include the oxygen mask, wherein the elastic bands are affixed at two (claims 7 and 10, page 4, lines 3-7; Figures 1 and 2) or four points (claims 6 and 9, page 4, lines 3-7; Figures 1 and 2). The oxygen mask also comprises a nosepiece with exhalations ports (claims 11-13, 17 and 18; Figures 1 and 2).

(G) GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL:

Claims 5-10 and 12-14[1] stand finally rejected under 35 U.S.C. 103(a) as unpatentable over Hudson (US Patent No. 2,843,121 taken in view of Bledstein (US Patent No. 5,701,892).

Claims 12, 13, and 18 stand finally rejected under 35 U.S.C. 103(a) as being unpatentable over Hudson (US Patent No. 2,843,121 taken in view of Bledstein (US Patent 5,701,892), as applied to the claims 5-10 and 12-14 when taken in further view of Laanen et al. (US Patent No. 4,865,027).

(H) APPELLANT'S ARGUMENTS:

The Rejection of Claims 5-10 and 12-14 under 35 U.S.C. 103(a):

Claims 5-10 and 12-14 stand rejected by the Examiner[2] as being unpatentable over Hudson (US Patent No. 2,843,121) in view of Bledstein (US Patent No. 5,701,892). The Examiner, initially, asserted that

> "[a]s to claims 5, 7, 8, and 10, Hudson teaches an oxygen mask 10 having a means for being secured over the nose and mouth of a patient comprising: an elastic band, points of attachment 15 on both sides of the mask, and the elastic band securable to the patient by pulling the ends anteriorally through the points of attachment (col. 2, lines 27-31)."

The Examiner acknowledges that Hudson "fails to teach a pair of bands extendible to loop over and around each ear of the patient."

The Examiner relies on Bledstein as teaching " a mask that uses a pair of bands affixed at four points of attachment and extendible to loop over and around each ear of a patient."

The Examiner concludes that "it would have been obvious to one of ordinary skill in the art at the time of invention was made to replace band 17 (of Hudson) with ear loops of Bledstein

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[1] While not specifically addressed in the statement of rejection in the Final Rejection of January 22, 2007, claims 15 and 17 were addressed in the explanation of the rejection. Therefore, the present discussion includes arguments relating to these claims, in addition to those specifically rejected.
[2] Final Rejection of January 22, 2007.

to prevent entanglement of bands in a user's hair, glasses, or hat and to make it easy to put on (col. 2, lines 32-33 and col. 6, lines 10-17)." (Final Rejection, pages 4-7).

The Examiner further notes that:

> [a]s to claims 6 and 9, Hudson/Bledstein teaches wherein the elastic bands are affixed at four separate points on the mask.
>
> [a]s to claim 14 Hudson teaches an oxygen mask for use on a patient - - - comprising: a face mask molded from plastic comprising a larger part of the mask defined by a face-conforming periphery, a rim with an enlargement configured to substantially conform to the contour of the nose bridge of the patient; a first side portion and an opposite second side portion configured to substantially conform to contour of the face of the patient, and a lower portion configured to substantially conform to contour of the face of the patient below the mouth so as to form a breathing chamber about the mouth and nostrils of the patient (see figures). (Final Rejection, paragraph bridging pages 6-7).
>
> The Examiner acknowledges that "Hudson fails to teach a pair of bands extendible to loop over and around each ear of the patient." (Id.)

However, the Examiner again relies on the Bledstein reference urging that it:

> "teaches a mask that uses a pair of bands affixed at points of attachment and extendible to loop over and around each ear of a patient."

The Examiner, then concludes that:

> "it would have been obvious to one having ordinary skill in the art at the time the invention was made to replace band 17 with ear loops of Bledstein to prevent entanglement of bands in a user's hair, glasses, or hat and to make it easy to put on (col. 2, lines 32-33 and col. 6, line 10-17). Hudson/Bledstein teaches wherein the elastic bands are affixed at four separate points on the mask." (Final Rejection, page 7, paragraph 11).

As to claim 15, the Examiner urges that "Hudson/Bledstein teaches the oxygen mask of claim 14, wherein both ends of the straps is adjustably connected to the face mask (col. 2, lines 20-31)," (Final Rejection, page 7, paragraph 12).

As to claim 17, the Examiner stated that "Hudson/Bledstein teaches the oxygen mask of claim 14, which additionally comprises an adapter plug 23." (Final Rejection, page 7, paragraph 13).

Appellant, respectfully, disagrees.

Appellant would urge that the evidence provided and relied upon by the Examiner, in the present rejection, does not provide an adequate factual basis on which to properly conclude that the presently claimed invention would have been obvious within the meaning of 35 U.S.C. 103(a) and that for the reasons provided below the rejection should not be sustained on appeal.

Initially, it should be noted that Claim 5 is directed to an oxygen mask comprising the following components:

1) an oxygen mask
2) a pair of elastic bands
3) both ends of each band is affixed at points of attachment on each side of the oxygen mask
4) both bands are extendible to loop over the ears
5) each band is adjustable by pulling the ends anteriorally through the point of attachment.

Claim 6 depends on claim 5 and further provides that the elastic bands are affixed at 4 separate points on the mask. Claim 7 is similar, but provides that the elastic bands are affixed at 2 separate points on the mask. Claim 8, 9 and 10 are similar in scope and limitations to claims 5-7, respectively. Claim 14 is similar to claim 5 but includes more detail about the nature and structure of the mask portion. However, claim 14 differs from claim 5 in providing that the oxygen mask comprises:

i) a first loop comprising a strap attached to the periphery of the mask at each of two points of attachment, said strap attached to said attachment points and connected to the face mask proximate the first side of the rim in a spaced apart relation to one another, with at least one loose end of the strap extending anteriorally through the attachment point;

ii) a second loop comprising a strap extending from an opposing side of the loop at a second juncture and being connected to the fac4e mask proximate the second side of the rim in a spaced apart relation to one another, with at least one loose end of the strap extending anteriorally through the attachment point;

iii) wherein said loose ends of the straps extend anteriorally through the attachment point such that adjustment of said straps can be effected by anteriorally pulling the loose ends secured at the attachment points; and

iv) the straps are sized and oriented relative to one another such that when the face mask and the strap assembly are operably donned on the patient each of the first and second straps is positioned substantially around a corresponding ear of the patient and has a length which extends approximately from a front side of the patient's ear to a rear side of the patient's ear to hold the mask securely on the patient's face.

Claim 15 depends from claim 14 and provides that both ends of the elastic bands are to be adjustable. Claim 17, similarly, depends from claim 14 and provides for the presence of an adapter plug to permit connection to the mask of an oxygen reservoir bad, air entrainment device or a nebulizer. However, given their dependency on claim 14, each requires the same elements of the attachment and adjustment of the elastic bands to the mask portion.

When the present claims are compared to the disclosure of Hudson (US Patent 2,843,121), one is drawn to the conclusion that the mask of Hudson differs significantly from that of the present invention. Hudson does not describe a pair of elastic bands and therefore can not disclose or describe the attachment of such a pair of bands to the sides of the oxygen mask. Further, there is no mention of looping the pair of bands over the ears of a patient. The Examiner has focused only on the absence of the pair of elastic bands as compared to the single band disclosed. However, there is nothing in Hudson which would suggest the need to use any other type of system to hold the oxygen mask on the patient in need of such treatment.

Hudson only has *one* of elastic band and does not disclose *a pair* of elastic bands on each side, as required by the claims. Also, Appellant note that col. 2, lines 36-38 states that the comfortable wearing position is "just below the ears," which teaches away from the invention, which requires that the bands extend to loop over and around each ear of the patient, as included in independent claims 5, 8 and 14. Additionally, the '121 patent teaches away from the invention in col. 2, lines 30-32, wherein the strap of the mask "can readily be moved only by pinching the strap together adjacent the opening, forcing it into a relatively rounded shape and then pulling it." This type of strap adjustment, also exemplified in Figure 6, is a strap that is folded through the opening with the construction such that the strap is not readily moved, particularly with one hand; the act of rounding the strap to force it through a round hole then pulling the strap would require the use of two hands, and unnecessary movement of the patient, particularly in emergency response services wherein patients may have neck and spinal injuries and one hand of the attendant is often occupied in other tasks (see page 2, lines5-16 of the specification). The strap of the '121 patent are not moved by simply pulling anteriorally on the strap, as claimed herein, but by pinching the straps to make them round, then pulling on them,

especially as claim 3 of the '121 patent requires a flat strap and a round hole (see Figures 4 and 6).

Additionally, the appellant cites MPEP 2143.01, which states: If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious.

The Examiner has cited Bledstein (US Patent No. 5,701,892) as providing that which is missing from the Hudson disclosure. In discussing Bledstein, the Examiner has said that the mask is suitable for use by a "patient." However, no where in Bledstein is there any reference to the use of this mask with a "patient" as would be appropriate for the currently claimed oxygen mask. In fact, that the person for which Bledstein suggests this mask is useful in that it "enhances the lives of people with respiratory disorders or professions which require respiratory protection." There is nothing which would suggest that the mask disclosed or any element thereof might be appropriate for use in a patient in need of oxygen and therefore the application of an oxygen mask. Clearly the disclosed mask is a filtration system and would not serve as an oxygen mask as presently claimed.

Further, as motivation for combining the teaches of Hudson and Bledstein, the Examiner cites from the Specification of Bledstein urging that "the ear loops of Bledstein to prevent entanglement of bands in a user's hair, glasses, or hat and to make it easy to put on (col. 2, lines 32-33 and col. 6, line 10-17)." (supra). The Examiner chooses to ignore the rest of this paragraph which specifically describes the type of attachment of the elastic bands contemplated by the patentee. Specifically, the disclosure at column 6, lines 10-19 which reads:

> Numerous convenient means for fastening a mask to the head of the wearer are contemplated. In the embodiments shown in FIGS. 1-2, and 4-5, **permanently attached**

> ear loops or straps 14 of elastic or other suitable cord material **of adjustable length** make the mask easy to put on and to fit snugly without interfering with hairdo, glasses, goggles, or hat. Other contemplated fastening means include **a permanently attached elastic strap** or core of suitable material that encircles the head below or above the ears and is easily **adjusted by means of a cord stop.**

Clearly this system differs from the presently claimed invention in that the elastic or cord material is permanently attached to the mask. Also, in both situations described, adjustment is of a method which does not involve "pulling the ends anteriorally through the point of attachment."

Thus, even if one were to substitute the strap system of Bledstein for the single strap system of Hudson one would not arrive at the presently claimed invention. The straps would be permanently attached to the mask, not adjustable by "pulling the ends anteriorally through the point of attachment" as required by claim 5, as well as claims 6-10 which include the same limitation. This deficiency of the Examiner's position is even more marked when this rejection is reviewed as to Claim 14 and the claims which depend therefrom. As noted above, claim 14 requires a specific relationship between the mask, the elastic bands, the attachment to the oxygen mask and the adjustability of the elastic bands. To the extent that the Examiner would urge that Hudson discloses an adjustable elastic band, appellant would note that no where in Hudson, does the reference state or describe the adjustment of the fit of the disclosed mask using a pull through technique as presently claimed. Why the Hudson system would appear to be capable of tightening the fit by pulling the single strap through the attachment hole, the only disclosure relating to this portion of the device would suggest that Hudson regarded this as a release mechanism for removing the mask in question. Specifically, Hudson in describing the attachment means states:

> A strap 17 installed in this manner will hold its position very well against considerable pull and **can readily be moved only by pinching the strap** 17 together

> adjacent the opening, forcing it into a relatively rounded shape and then pulling. (Emphasis added) (Col. 2, lines 28-32).

The, neither Hudson, which only includes a single strap, nor Bledstein, which disclosed two bands, but requires a fixed means of attachment with a differing system for adjustment, address these claim limitations in a manner which would reasonably support a conclusion of obviousness under 35 U.S.C. 103(a).

Thus, appellant would urge that the Examiner as failed to establish a prima facie case of obviousness within the meaning of 35 U.S.C. 103(a). In a rejection under 35 USC § 103(a), the Examiner bears the initial burden of establishing a prima facie case of obviousness. To establish a prima facie case of obviousness, there must be both some suggestion or motivation to modify the reference or combine reference teachings and a reasonable expectation of success. In re Vaeck, 947 F.2d 488, 493, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991). It is insufficient that the prior art discloses the components of the claimed invention, either separately or in other combinations; there must be some teaching, suggestion, or incentive to make the combination made by appellants. Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1143, 227 USPQ 543, 551 (Fed. Cir. 1985) (insufficient to select from the prior art the separate components of the inventor's combination, using the blueprint supplied by the inventor). To the extent that the Examiner urges that the use of the straps of Bledstein would "prevent entanglement of bands in a user's hair, glasses, or hat and make it easier to put on" appellant would urge that these considerations or purposes have not been shown to be applicable to the oxygen mask of the present invention or that of Hudson. These are aesthetic issues and of little importance when dealing with a situation which suggests the need of an oxygen mask.

Clearly, the present rejection represents a picking and choosing of elements from of two references, with a disregard as to those elements of the disclosure of each which might suggest that the combination is inappropriate. The courts have ruled that such selection of elements is not proper in a rejection relating to the obviousness of an invention. In other words, "[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention." In re Fine, 837 F.2d 1071, 1075, 5 USPQ2d 1596, 1600 (Fed. Cir.1988). "[T]here still must be evidence that 'a skilled artisan, . . . with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed.'" Echolochem. Inc. v. Southern California Edison, 227 F.3d 1361, 1375, 56 USPQ2d 1065, 1075-76 (Fed. Cir. 2000). Such evidence is missing in the instant rejection. There is nothing in this record which would readily suggest the combination of these two teachings other than appellant's own disclosure of the invention.

In addition, in putting together the reasoning and evidence in support of this rejection the Examiner has failed to account for each and every claim limitation of the present claims. Specifically, as discussed above, the limitation of claim 5 and particularly those limitations noted as to claim 14 have not been accounted for. To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). (See also, MPEP, section 2146.03).

Thus, the rejection is doubly flawed, the Examiner has failed to provide that level of evidence which would reasonably establish a prima facie case which would support a conclusion of obviousness and the rejection should be reversed on appeal.

Should the Board reviewing this application determine that the Examiner has, in fact, provided a level of evidence sufficient to support a conclusion of obviousness, Appellant would

urge that the evidence of record, which establishes a long felt need in the field for this type of oxygen mask, which has not been met by any product currently available, should be regarded as sufficient to overcome even this prima facie case. The oxygen mask of the present invention is regarded by practitioners in the field as satisfying what has been a long-felt need in the emergency services for a mask that can easily be placed without undue movement of the victim. Appellant provides Declarations by **Jonathan Van Zile, MD,** an Emergency Department Physician, Disaster team director, and EMS Medical Director for the Hamilton County-wide (police and EMS) Communications Center (an integrated county-wide 911 center), Medical Director for the Amusement park, Kings Island (sister park to "Kings Dominion") and Medical Director for three (3) City Ambulance services (known in Ohio as "Life Squads") (20 years experience); **Judy Levy, RN, BSN,** an Emergency Department nurse and EMS Coordinator and Paramedic Training Director and Supervisor (33 years experience); **Kathleen Ballman, RN, BSN, MSN**, a Registered Nurse Practitioner, an Emergency Department nurse providing direct respiratory care and Heart Failure Specialist (30 years experience); **Raymond P. Mueller, Jr., RN, Paramedic,** who works in cardiac intensive care (18 years experience as an RN, 27 years experience as a Paramedic); and **Sandra Wolf Tomlin**, a Registered Respiratory Therapist (30 years experience). These persons of ordinary skill in the art at all levels of emergency and critical care, with a combination of 140 years of experience, have declared that the mask of the invention is both needed in the field and not currently provided in the market. All of them are aware of the state of the art and the various masks and attachments on the market and state the need of the claimed invention in the market and the absence of the claimed invention in the market. If these persons of ordinary skill in the art are aware of the current art and find the invention to be new and unobvious, then Examiner's assertions that "it is well know [sic] in the

art of masks that the use of a pair of bands in an alternative for one band" is not properly applied and the rejection must be withdrawn. The Examiner has yet to act on the After-final Reply filed June 20, 2007, or the Affidavits under 37 C.F.R. 1.132, so they are as of yet, not entered.

Regarding the dependent claims, the Examiner has not established a *prima facie* case of obviousness as to the independent claims 5, 8 and 14, for the reasons set forth above. It follows that the Examiner's comments regarding the dependent claims are similarly flawed. It is noted that claims 12 and 13 are grouped with the present rejected claims. However, the Examiner has not addressed these claims in setting forth the basis for rejection. Since these claims include and thus require limitations not present in either Hudson or Bledstein, as acknowledged in the following rejection under 35 U.S.C. 103(a), it follows that these claims are improperly rejected under 35 U.S.C. 103(a) over the combination of these two references.

The Rejection of Claims 12, 13, and 18

At pages 7-8 of the Final Rejection of January 22, 2007, the Examiner sets forth the reasoning in support of the rejection of claims 12, 13 and 18. Claims 12, 13, and 18 were rejected by the Examiner under 35 U.S.C. 103(a) as being unpatentable over Hudson/Bledstein as applied to the claims above, and further in view of Laanen et al. (US Patent No. 4,865,027).

The Examiner notes that "Hudson/Bledstein teaches the mask of claims 5 and 8.

The Examiner acknowledges that "Hudson/Bledstein fails to specifically teach the use of a flap valve."

However, the Examiner cites Laanen et al. stating that Laanen et al. "teaches a mask with a common valve (20) to vent exhaled gases.

Based on these facts the Examiner concludes that "it would have been obvious to one having ordinary skill in the art at the time the invention was made to use a valve to allow exhaled air to be forced out to the atmosphere (col. 4, lines 58-60)."

Initially, appellants would note that claims 12, 13 and 18 depend from claims 5, 8, and 14, respectively, and therefore include all limitations therein. In addition, claims 12, 13 and 18 provide that the mask additionally comprises a nosepiece with 2 exhalation ports covered by a flap value. Since this rejection, as with the rejection of claims 5-10, 12-14, 15 and 17 is based on the initial combination of Hudson in view of Bledstein, appellant would urge that this rejection is flawed for all of the reasons set forth above as to that ground of rejection. Thus, this ground of rejection should, also, not be sustained and the rejection should be reversed.

In addition, appellant for note that this ground of rejection is additionally flawed. The Examiner has concluded, without any real explanation, that it would have been obvious within the meaning of 35 U.S.C. 103(a) to include the flap value system of Laanen et al., presumably into the mask of either Hudson or Bledstein. Appellant disagrees.

Initially, appellant would note that neither Hudson nor Bledstein disclose the use of a flap covered value in the masks described by the respective references. Hudson, in particular, goes into a rather extensive disclosure of the port to be used in that mask. Specifically, Hudson provides at column 2, that:

> Another important feature of the invention is the novel exhalation opening 20, which consists of a large plurality of small openings 21, instead of a single large opening. --- For the small openings 21 create more resistance than did a single large opening having the same total area. Furthermore, I have found that the mental state of the patient is more reassured by the plurality of openings 21 than by a single large one. -----.

Thus, it is clear that Hudson, specifically prefers a series of small openings and in addition, prefers for several stated reasons, the specific arrangement disclosed. The Examiner

fails to explain why it would have been obvious to modify this particular mask in the manner necessary to arrive at the claimed invention, when such a modification would go directly against the specific intention of the Patentee in this situation.

Similarly with Bledstein, the air holes are said to be "reinforced", but there is no suggestion or teaching why one would desire a port with a flap value.

Thus, it remains that the Examiner's rejection of claims 12, 13, and 18 fail to provide the suggestion, direction or motivation which would reasonably support the combination of Hudson and Bledstein with the additional reference Laaner et al. See e.g., Pro-Mold and Tool Co. v. Great Lakes Plastics Inc., 75 F.3d 1568, 1573, 37 USPQ2d 1626, 1629 (Fed. Cir. 1996) ("[i]t is well-established that before a conclusion of obviousness may be made based on a combination of references, there must have been a reason, suggestion or motivation to lead an inventor to combine those references."). In the instant rejection that combination is lacking.

Thus, appellant would urge that the present rejection of claims 12, 13, and 18 fail to provide that level of evidence which would reasonably support a conclusion that the presently claimed invention would have been obvious within the meaning of 35 U.S.C. 103(a). Therefore, appellant requests that this ground of rejection be reversed.

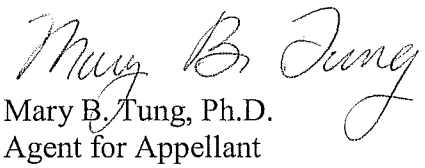
Conclusion

Claims 5-10, 12-15, 17 and 18 are under consideration by the Examiner. The Appellant respectfully requests consideration of the application in view of the Remarks and Declarations submitted herewith. The Appellant requests that the Declarations be entered in the present application as the Declarations present convincing evidence that the claims are patentable over the references cited by the Examiner; that the Declarations place the application in better condition for allowance and/or appeal; and that the Declarations do not raise new issues or introduce new matter.

In view of the above remarks, Appellant respectfully submits that the application and claims are in condition for allowance, and request that the Examiner reconsider and withdraw the objections and rejections. Appellant believes that a full and complete reply has been made to the outstanding Office action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Reply is respectfully requested.

Respectfully submitted,



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Claims Appendix

Pending claims:

5. An oxygen mask comprising a pair of elastic bands, both ends of each pair affixed at points of attachment to each of both sides of said oxygen mask, said bands extendible to loop over and around each ear of the patient and adjustably securable to said patient by pulling the ends anteriorally through said points of attachment.

6. The oxygen mask according to claim 5 wherein the elastic bands are affixed at four separate points on the mask.

7. The oxygen mask according to claim 5 wherein the elastic bands are affixed at two separate points on the mask.

8. An oxygen mask having an improved means for being secured over the nose and mouth of a patient, wherein the oxygen mask comprises a pair of elastic bands, both ends of each pair affixed at points of attachment to each of both sides of said oxygen mask, said bands extendible to loop over and around each ear of the patient and adjustably securable to said patient by pulling the ends anteriorally through said points of attachment.

9. The oxygen mask according to claim 8 wherein the elastic bands are affixed at four separate points on the mask.

10. The oxygen mask according to claim 8 wherein the elastic bands are affixed at two separate points on the mask.

12. The mask of claim 5, wherein said mask comprises a nosepiece with two exhalation ports covered with a flap valve.

13. The oxygen mask of claim 8, wherein said mask comprises a nosepiece with two exhalation ports covered with a flap valve.

14. An oxygen mask for use on a patient, said oxygen mask comprising:

a) a face mask molded from plastic to form a soft, one-piece covering for the mouth and nose of the patient, comprising a larger part of the mask defined by a face-conforming periphery, having a rim with an enlargement configured to substantially conform to the contour of the nose bridge of the patient;

a first side portion and an opposite second side portion configured to substantially conform to the contour of the face of the patient, and a lower portion configured to substantially conform to the contour of the face of the patient below the mouth so as to form a breathing chamber about the mouth and nostrils of the patient when the oxygen mask is positioned on the patient's face; and

b) a pair of elastic bands, both ends of each pair affixed to each of both sides of said mask, said bands extendible to loop over and around each ear of the patient for holding the face mask snugly against the patient's face, the straps comprising a left and right loop strap;

i) a first loop comprising a strap attached to the periphery of the mask at each of two points of attachment, said strap attached to said attachment points and connected to the face mask proximate the first side of the rim in a spaced apart relation to one another, with at least one loose end of the strap extending anteriorally through the attachment point;

ii) a second loop comprising a strap extending from an opposing side of the loop at a second juncture and being connected to the face mask proximate the second side of the rim in a spaced apart relation to one another, with at least one loose end of the strap extending anteriorally through the attachment point;

iii) wherein said loose ends of the straps extend anteriorally through the attachment point such that adjustment of said straps can be effected by anteriorally pulling the loose ends secured at the attachment points; and

iv) the straps are sized and oriented relative to one another such that when the face mask and the strap assembly are operably donned on the patient each of the first and second straps is positioned substantially around a corresponding ear of the patient and has

a length which extends approximately from a front side of the patient's ear to a rear side of the patient's ear to hold the mask securely on the patient's face.

15. The oxygen mask of claim 14, wherein both ends of each of the straps is adjustably connected to the face mask.

17. The oxygen mask of claim 14, which additionally comprises an adapter plug attached adjacent to the nostrils, for the attachment of a tube attached to a device selected from the group consisting of an oxygen reservoir bag, air entrainment device, and nebulizer.

18. The oxygen mask of claim 14, wherein said mask comprises a nosepiece with two exhalation ports covered with a flap valve.

Evidence appendix

None

Related proceedings appendix

None